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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,086	01/27/2004	Ashvinikumar V. Gavai	LA0074 NP	2426

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EXAMINER

FREISTEIN, ANDREW B

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/766,086

Applicant(s)

GAVAI ET AL.

Examiner

Andrew B. Freistein

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☒ Claim(s) 1,2,4,5 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/6/04, 9/2/04, 11/22/04

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

Claims 1-13 are currently pending in the instant application.

***Priority***

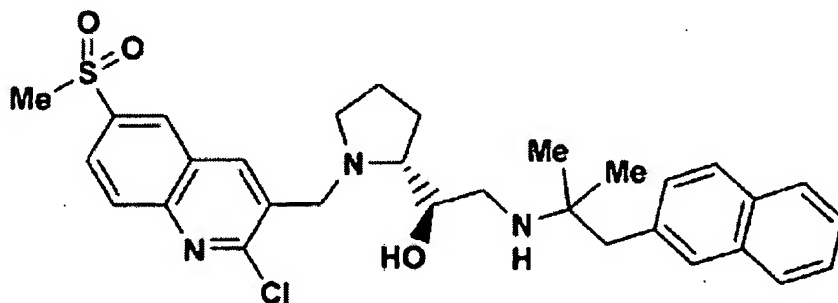
This application claims benefit of US Provisional Application No. 60/443,255, filed on 01/28/2003.

***Information Disclosure Statement***

Applicants' information disclosure statements (IDSs), filed on 08/06/2004, 09/02/2004, and 11/22/2004, have been considered. Please refer to Applicants' copies of the 1449 submitted herewith.

***Response to Restriction Requirement***

Acknowledgement is made of Applicants' election (with traverse) of Group I, claims 1-7, and the species



, in a response filed

08/15/2005.

Applicants traverse the restriction requirement asserting that claims 12 and 13 should be included in Group I, because the claims do not require a therapeutic agent in addition to the compound of claim 1. Secondly, Applicants traverse the restriction requirement, because the claims (1) share a common utility and (2) share a common

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structural feature in formula I. Thirdly, Applicants traverse the requirement to elect a species for search purposes.

The Examiner respectfully disagrees with the Applicants because the products of Inventions I-III differ materially in structure and element and from each other and are therefore capable of supporting their own patents. The invention groups I-III are related to a set of structurally diverse compounds, their methods of use, and pharmaceutical compositions with intended use. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The chemical structures claimed do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Due to the plethora of classes and subclasses in each of group, separate search considerations are involved, which would impose a serious burden on the Examiner.

Nevertheless, Examiner may reconsider to rejoin the method of use claims and the pharmaceutical composition claims commensurate in scope with the product claims when and if the case is found to be in condition for allowance provided those method of use claims and pharmaceutical composition claims are free of 35 U.S.C. § 112 first and second paragraph issues (including written description, reach-through claim language and/or scope of enablement issues).

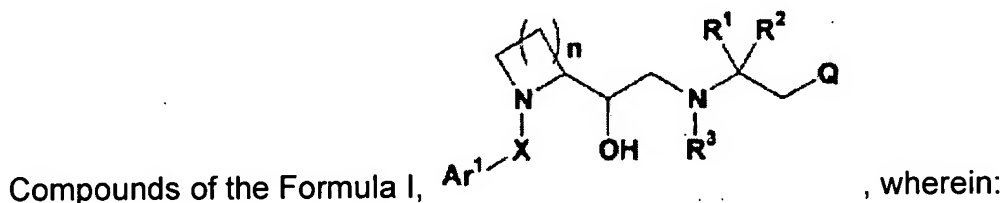
Applicants reserve their right to file a divisional application on the non-elected subject matter.

***Status of the Claims***

Claims 1-7 (in part), are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

**Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



**Ar<sup>1</sup>** is a substituted or unsubstituted heteroaryl consisting of one Nitrogen and five Carbons, that may be part of a bicyclic ring system;

**X** is as defined in claim 1;

**n** is as defined in claim 1;

**R<sup>1</sup>** is as defined in claim 1;

**R<sup>2</sup>** is as defined in claim 1;

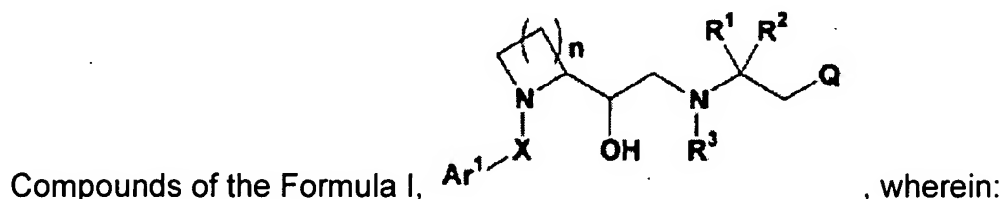
**R<sup>3</sup>** is as defined in claim 1; and

**Q** is substituted or unsubstituted aryl.

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Non-elected and Non-examined Subject Matter

The scope of the invention of the non-elected and non-examined subject matter is as follows:



**Ar<sup>1</sup>** is a substituted or unsubstituted aryl, or substituted or unsubstituted heteroaryl other than a heteroaryl consisting of one Nitrogen atom and five Carbon atoms, that may be part of a bicyclic ring system;

**Q** is G or Ar<sup>1</sup> as defined above;

**G** is as defined in claim 1;

**Z** is as defined in claim 1;

**R<sup>4</sup>** is as defined in claim 1;

**R<sup>5</sup>** is as defined in claim 1; and

**R<sup>6</sup>** is as defined in claim 1.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of Claims 1-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as thiazolidine, piperazine, thiophene, morpholine, oxazol, pyrimidine, pyrazine, pyran, etc. which are chemically recognized to differ in structure, function, and reactivity.

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Therefore, the subject matter which was withdrawn from consideration as being non-elected subject matter materially differs in structure and composition from the elected/examined subject matter so that a reference which anticipates the elected/examined subject matter would not render obvious the non-elected subject matter.

### ***Claim Rejections - 35 USC § 112***

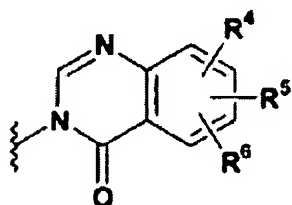
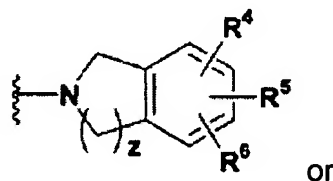
The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

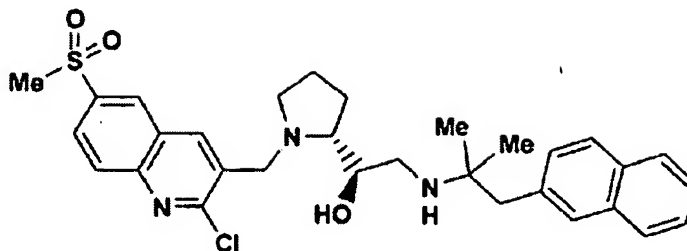
Claims 1-3, and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 defines Ar<sup>1</sup> to be, "a substituted or unsubstituted aryl or substituted or

unsubstituted heteroaryl" and defines Q to be, "Ar<sup>1</sup> or G." G is



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The elected species is:

which has a quinoline bonded to X as Ar<sup>1</sup>. Q is naphthalene and therefore cannot be G.

Thus, Q must be Ar<sup>1</sup>. However, Ar<sup>1</sup> is quinoline. Thus, the definition of Ar<sup>1</sup> is ambiguous because it has one definition, but two different possibilities.

Applicants can overcome this rejection by changing the definition to Q to be independent of Ar<sup>1</sup>.

### ***Claim Objections***

Claims 2-7 are objected to as being dependent upon a rejected base claim.

Claims 1, 2, 4, 5, and 7 are objected to as containing non-elected subject matter.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626

for   
\_\_\_\_\_  
Joseph K. McKane

Supervisory Patent Examiner, AU 1626  
Date: November 11, 2005